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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/129,298	08/05/1998	CHARLES J. ARNTZEN	7991-023-999	4312

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/129,298

Applicant(s)

ARNTZEN ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 8-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. The request filed on 26 February 2003 for a Continued Prosecution Application (CPA) under 37 CFR § 1.53(d) based on parent Application No. 089/129,298 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 1-4 and 8-27 are pending.

Status of the Application

3. This Office action is in response to the Amendment and Remarks filed on 26 February 2003.
4. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

6. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). In the instant case, the first line of the specification must be amended to read -- This application claims benefit of U.S. Provisional Application 60/054,836, filed August 5, 1997. --. See MPEP § 201.11(III)(B).

Claim Rejections - 35 USC § 112

7. Claims 1-4 and 8-27 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of making a localized mutation in a target plant ALS gene or a transgenic GFP gene *in situ* in a plant cell, does not reasonably provide enablement for a method of making a localized mutation in any target gene in a plant cell. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 September 2002. Applicant's arguments filed 26 February 2003 have been fully considered but they are not persuasive.

Applicant argues that the presently claimed process can be used with a high degree of certainty once the gene sequence of a plant is known (paragraph spanning pages 5-6 of the Remarks). Applicant argues because the DNA sequence is known, and RO (recombinogenic oligonucleobase) can be prepared that has the requisite homologous and heterologous regions required by the claims and the introduced RO then performs its function and makes the mutation resulting in the desired trait in the plant cell (page 6, 3rd paragraph of the Remarks). This argument is not found to be persuasive for the reasons given in the previous Office actions, that being at the time of Applicant's invention, the claimed process had not been shown to be predictable and the art teaches, after Applicant's filing, that the nature of the claimed process is unpredictable because the mismatch repair system in plants does not operate in the predictable manner of that of mammalian and fungal cells. In addition, Applicant does not teach how or practice the claimed process in a predictable manner. As directed to claims 1 and 16, said claims are to methods of making a localized mutation in a plant

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cell to a target gene having a know sequence, said methods of making a localized mutation in a plant cell being unpredictable and requiring undue trial and error experimentation by one of skill in the art at the time of Applicant's invention.

Claim Rejections - 35 USC § 102

8. Claims 1 and 16 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Svab *et al* 1990 (Proc. Natl. Acad. Sci. USA 87:8526-8530). This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 September 2002. Applicant's arguments filed 26 February 2003 have been fully considered but they are not persuasive.

Applicant argues that claim terms are read in view of the definitions of those terms appearing in the Specification and that the instant claimed invention does not read one, encompass or contemplate transformation with transgenes (pages 3-4 of the Remarks). This argument is not found to be persuasive because while the claims are read in light of the specification, they are not limited to the teachings of the specification. Applicant's definition on pages 1-4 of the specification as directed to a recombinagenic oligonucleobase is exemplary, and not limiting. The mutant gene disclosed by Svab *et al* has the properties of the recombinagenic oligonucleobase cited in the claimed invention. In addition, one of skill in the art would have recognized that the oligonucleobase disclosed by Svab *et al* could function in an identical manner as that taught by Applicant in the mixed duplex oligonucleotides.

Claim Rejections - 35 USC § 103

9. Claims 1-4 and 8-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kmiec (U.S. Patent 5,731,181, filed 17 June 1996) in view of Dunder *et al* (in Gene Transfer To Plants 1995, Potrykus and Spangenberg, Eds., Springer Verlag publisher, Chapter 15, pages 127-138) and in view of Applicant's admission. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 September 2002. Applicant's arguments filed 26 February 2003 have been fully considered but they are not persuasive.

Applicant argues that the effects of the harsh chemical and physical conditions seen in the prior art DNA biolistic transformation on the fragile RO was unknown at the time of the present invention and that Applicant's confirmed that the biolistic process did indeed work as described in the specification (page 6, 2nd paragraph of the Remarks). Applicant argues that the fragile nature of the RO and harsh chemical and physical conditions used in the prior art biolistics transformation art with large molecules and total lack of expectation of success found in the prior art lead only to a conclusion of nonobviousness (paragraph spanning pages 6-7 of the Remarks). These arguments are not found to be persuasive because Applicant provides no evidence that teach away from the claimed invention. The example taught by Dunder *et al* on page 135 uses 1.02 M CaCl₂, a functional equivalent of NaCl, and 16 µM spermidine, which would be within the range of obvious experimentation of that of claim 8. Given the teachings of Kmiec and Dunder *et al*, the instant claimed invention would have been obvious to do, and one of ordinary skill in the art would have had a reasonable expectation of success.

Conclusion

10. No claims are allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'David H. Kruse', with a stylized, cursive script.

David H. Kruse, Ph.D.
22 September 2003